Complete Summary

GUIDELINE TITLE

Poliomyelitis prevention in the United States.

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Poliomyelitis prevention in the United States. MMWR Recomm Rep 2000 May;49(RR-5):1-22. [81 references]

GUIDELINE STATUS

This is the current release of the guideline.

Update: These revised recommendations replace recommendations on poliomyelitis issued in 1982 (Poliomyelitis prevention: recommendations of the Immunization Practices Advisory Committee [ACIP]. Morbid Mortal Wkly Rep MMWR 1982;31), 1987 (Poliomyelitis prevention: enhanced-potency inactivated poliomyelitis vaccine-supplementary statement: recommendations of the Immunization Practices Advisory Committee [ACIP]. Morbid Mortal Wkly Rep MMWR 1987;36:795-8) and 1997 (Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine. Recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR Morb Mortal Wkly Rep 1997 Jan 24;46(RR-3):1-25).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Poliomyelitis

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To revise recommendations of the Advisory Committee on Immunization Practices (ACIP) for poliomyelitis prevention and to describe ACIP's rationale for exclusive use of inactivated poliovirus vaccine (IVP) for routine childhood polio vaccination in the United States.

TARGET POPULATION

Infants, Children, Unvaccinated Adults

INTERVENTIONS AND PRACTICES CONSIDERED

Poliovirus vaccination:

- Inactivated poliovirus vaccine (IPV), for routine childhood polio vaccination in the United States

  Note: two IPV vaccine products are licensed in the United States (U.S.), IPOL® and POLIOVAX®, although only IPOL® is distributed in the U.S. Both products consist of three types of poliovirus: type 1 (Mahoney), type 2 (MEF-1), and type 3 (Saukett).

- Oral poliovirus vaccine (OPV), for countries where polio is endemic or for outbreak control

MAJOR OUTCOMES CONSIDERED

- Seroconversion rates (percent of vaccine recipients with detectable antibodies)
- Vaccination levels (percent of children immunized)
- Incidence of vaccine-associated paralysis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Highlights of changes from previous recommendations:

In 1997, the Advisory Committee on Immunization Practices (ACIP) recommended using a sequential schedule of inactivated poliovirus vaccine (IPV) followed by oral poliovirus vaccine (OPV) for routine childhood polio vaccination in the United States, replacing the previous all-OPV vaccination schedule. This change was intended to reduce the risk for vaccine-associated paralytic poliomyelitis (VAPP). Since 1997, the global polio eradication initiative has progressed rapidly, and the likelihood of poliovirus importation into the United States has decreased substantially. The sequential schedule has been well accepted, and no declines in childhood immunization coverage have been observed. On the basis of these data, ACIP recommended on June 17, 1999, an all-IPV schedule for routine childhood polio vaccination in the United States to eliminate the risk for VAPP. ACIP also reaffirms its support for the global polio eradication initiative and the use of OPV as the only vaccine recommended to eradicate polio from the remaining countries where polio is endemic.

Recommendations for Inactivated Polio Virus (IPV) Vaccination

Routine Vaccination

All children should receive four doses of IPV at ages 2, 4, and 6-18 months and 4-6 years. The first and second doses of IPV are necessary to induce a primary immune response, and the third and fourth doses ensure "boosting" of antibody titers to high levels. If accelerated protection is needed, the minimum interval between doses is 4 weeks, although the preferred interval between the second and third doses is 2 months (see Recommendations for IPV Vaccination of Adults). All children who have received three doses of IPV before age 4 years should receive a fourth dose before or at school entry. The fourth dose is not needed if the third dose is administered on or after the fourth birthday.

Incompletely Vaccinated Children

The poliovirus vaccination status of children should be evaluated periodically. Those who are inadequately protected should complete the recommended vaccination series. No additional doses are needed if more time than recommended elapses between doses (e.g., more than 4-8 weeks between the first two doses or more than 2-14 months between the second and third doses).

Scheduling IPV Administration

Until appropriate combination vaccines are available, the administration of IPV will require additional injections at ages 2 and 4 months. When scheduling IPV administration, the following options should be considered to decrease the number of injections at the 2- and 4-month patient visits:

- Administer Hepatitis B at birth and ages 1 and 6 months.
- Schedule additional visits if there is reasonable certainty that the child will be brought back for subsequent vaccination at the recommended ages.
- Use available combination vaccines.

Interchangeability of Vaccines

Children who have initiated the poliovirus vaccination series with one or more doses of OPV should receive IPV to complete the series. If the vaccines are administered according to their licensed indications for minimum ages and intervals between doses, four doses of OPV or IPV in any combination by age 4-6 years is considered a complete series, regardless of age at the time of the third dose. A minimum interval of 4 weeks should elapse if IPV is administered after OPV. Available evidence indicates that persons primed with OPV exhibit a strong mucosal immunoglobulin A response after boosting with IPV.

Administration with Other Vaccines

IPV can be administered simultaneously with other routinely recommended childhood vaccines. These include DTP, DTaP, Hib, HepB, varicella (chickenpox) vaccine, and measles-mumps-rubella vaccine.

Recommendations for IPV Vaccination of Adults

Routine poliovirus vaccination of adults (i.e., persons aged $\geq$18 years) residing in the United States is not necessary. Most adults have a minimal risk for exposure to polioviruses in the United States and most are immune as a result of vaccination during childhood. Vaccination is recommended for certain adults who are at greater risk for exposure to polioviruses than the general population, including the following persons:

- Travelers to areas or countries where polio is epidemic or endemic.
- Members of communities or specific population groups with disease caused by wild polioviruses.
- Laboratory workers who handle specimens that might contain polioviruses.
- Health-care workers who have close contact with patients who might be excreting wild polioviruses.
- Unvaccinated adults whose children will be receiving oral poliovirus vaccine.

Unvaccinated adults who are at increased risk should receive a primary vaccination series with IPV. Adults without documentation of vaccination status should be considered unvaccinated. Two doses of IPV should be administered at intervals of 4-8 weeks; a third dose should be administered 6-12 months after the second. If three doses of IPV cannot be administered within the recommended intervals before protection is needed, the following alternatives are recommended:

- If more than 8 weeks are available before protection is needed, three doses of IPV should be administered at least 4 weeks apart.
- If fewer than 8 weeks but more than 4 weeks are available before protection is needed, two doses of IPV should be administered at least 4 weeks apart.
- If fewer than 4 weeks are available before protection is needed, a single dose of IPV is recommended.

The remaining doses of vaccine should be administered later, at the recommended intervals, if the person remains at increased risk for exposure to

poliovirus. Adults who have had a primary series of OPV or IPV and who are at increased risk can receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults

Precautions and Contraindications

Hypersensitivity or Anaphylactic Reactions to IPV or Antibiotics Contained in IPV

IPV should not be administered to persons who have experienced a severe allergic (anaphylactic) reaction after a previous dose of IPV or to streptomycin, polymyxin B, or neomycin. Because IPV contains trace amounts of streptomycin, polymyxin B, and neomycin, hypersensitivity reactions can occur among persons sensitive to these antibiotics. No serious adverse events related to use of enhanced-potency IPV have been documented.

Pregnancy

Although no adverse effects of IPV have been documented among pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. However, if a pregnant woman is at increased risk for infection and requires immediate protection against polio, IPV can be administered in accordance with the recommended schedules for adults (see Recommendations for IPV Vaccination of Adults).

Immunodeficiency

IPV is the only vaccine recommended for vaccination of immunodeficient persons and their household contacts. Many immunodeficient persons are immune to polioviruses as a result of previous vaccination or exposure to wild virus when they were immunocompetent. Administration of IPV to immunodeficient persons is safe. Although a protective immune response in these persons cannot be ensured, IPV might confer some protection.

False Contraindications

Breastfeeding does not interfere with successful immunization against polio. A dose of IPV can be administered to a child who has diarrhea. Minor upper respiratory illnesses with or without fever, mild to moderate local reactions to a previous dose of vaccine, current antimicrobial therapy, and the convalescent phase of an acute illness are not contraindications for vaccination.

Recommendations for Oral Poliovirus Vaccination (OPV)

Recommendations for OPV Vaccination for Outbreak Control

Rationale

As affirmed by ACIP, OPV remains the vaccine of choice for mass vaccination to control polio outbreaks. Data from clinical trials and empirical evidence support the effectiveness of OPV for outbreak control. The preference for OPV in an

outbreak setting is supported by a) higher seroconversion rates after a single dose of OPV compared with a single dose of IPV; b) a greater degree of intestinal immunity, which limits community spread of wild poliovirus; and c) beneficial secondary spread (intestinal shedding) of vaccine virus, which improves overall protection in the community.

As a live attenuated virus, OPV replicates in the intestinal tract and induces antibodies in more recipients after a single dose. Thus, OPV can protect more persons who are susceptible in a population, making it the preferred vaccine for rapid intervention during an outbreak. Among persons previously vaccinated with three doses of IPV or OPV, excretion of poliovirus from the pharynx and the intestine appears most closely correlated with titers of homologous humoral antibody. Three doses of either IPV or OPV induce protective antibody levels (neutralizing antibody titers >1:8) to all three serotypes of poliovirus in >95% of infant recipients. Therefore, boosting of immunity with a single dose of OPV or IPV is likely to reduce both pharyngeal and intestinal excretion of poliovirus, effectively stopping epidemic transmission of wild poliovirus.

Use of OPV for Outbreak Control

OPV has been the vaccine of choice for polio outbreak control. During a polio outbreak in Albania in 1996, the number of cases decreased 90% within 2 weeks after administration of a single dose of OPV to >80% of the population aged 0-50 years. Two weeks after a second round of vaccination with OPV, no additional cases were observed. Rapidly implemented mass vaccination campaigns resulting in high coverage appears to have been similarly effective in interrupting wild poliovirus outbreaks in other countries.

European countries that rely solely on IPV for routine poliovirus vaccination (e.g., the Netherlands and Finland) have also used OPV for primary control of outbreaks. During the 1992-93 polio outbreak in the Netherlands, OPV was offered to members of a religious community affected by the outbreak (who were largely unvaccinated before the outbreak) and other persons living in areas affected by the outbreak. IPV was given to immunized persons outside the outbreak areas to ensure protection in this population. During a 1984-85 polio outbreak in Finland, 1.5 million doses of IPV initially were administered to children <18 years for immediate boosting of protection. Later, approximately 4.8 million doses of OPV were administered to 95% of the population. In contrast, mass vaccination with IPV exclusively has had little impact on outbreaks and has rarely been used since OPV became available.

Recommendations for Other Uses of OPV

For the remaining non-emergency supplies of OPV, only the following indications are acceptable for OPV administration:

- Unvaccinated children who will be traveling in fewer than 4 weeks to areas where polio is endemic. If OPV is not available, IPV should be administered.
- Children of parents who do not accept the recommended number of vaccine injections. These children can receive OPV only for the third or fourth dose or both. In this situation, health-care providers should administer OPV only after discussing the risk for VAPP with parents or caregivers.

Precautions and Contraindications

Hypersensitivity or Anaphylactic Reactions to OPV

OPV should not be administered to persons who have experienced an anaphylactic reaction to a previous dose of OPV. Because OPV also contains trace amounts of neomycin and streptomycin, hypersensitivity reactions can occur in persons sensitive to these antibiotics.

Pregnancy

Although no adverse effects of OPV have been documented among pregnant women or their fetuses, vaccination of pregnant women should be avoided. However, if a pregnant woman requires immediate protection against polio, she can receive OPV in accordance with the recommended schedules for adults (see Use of OPV for Outbreak Control).

Immunodeficiency

OPV should not be administered to persons who have immunodeficiency disorders (e.g., severe combined immunodeficiency syndrome, agammaglobulinemia, or hypogammaglobulinemia) because these persons are at substantially increased risk for VAPP. Similarly, OPV should not be administered to persons with altered immune systems resulting from malignant disease (e.g., leukemia, lymphoma, or generalized malignancy) or to persons whose immune systems have been compromised (e.g., by therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation or by infection with human immunodeficiency virus [HIV]). OPV should not be used to vaccinate household contacts of immunodeficient patients; IPV is recommended. Many immunodeficient persons are immune to polioviruses as a result of previous vaccination or exposure to wild virus when they were immunocompetent. Although their risk for paralytic disease could be lower than for persons with congenital or acquired immunodeficiency disorders, these persons should not receive OPV.

Inadvertent Administration of OPV to Household Contacts of Immunodeficient Persons

If OPV is inadvertently administered to a household contact of an immunodeficient person, the OPV recipient should avoid close contact with the immunodeficient person for approximately 4-6 weeks after vaccination. If this is not feasible, rigorous hygiene and hand washing after contact with feces (e.g., after diaper changing) and avoidance of contact with saliva (e.g., sharing food or utensils) can be an acceptable but probably less effective alternative. Maximum excretion of vaccine virus occurs within 4 weeks after oral vaccination.

False Contraindications

Breastfeeding does not interfere with successful immunization against polio. A dose of OPV can be administered to a child who has mild diarrhea. Minor upper respiratory illnesses with or without fever, mild to moderate local reactions to a

previous dose of vaccine, current antimicrobial therapy, and the convalescent phase of an acute illness are not contraindications for vaccination.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Exclusive use of inactivated poliovirus vaccine (IPV) for childhood polio vaccination should eliminate the risk for vaccine-associated paralytic poliomyelitis (VAPP).

Advantages of oral poliovirus vaccine (OPV) in an outbreak situation compared to IPV include higher seroconversion rates after a single dose, a greater degree of intestinal immunity, which limits community spread of wild poliovirus; and beneficial secondary spread (intestinal shedding) of vaccine virus, which improves overall protection in the community.

POTENTIAL HARMS

In rare instances, administration of oral poliovirus vaccine (OPV) has been associated with paralysis in healthy recipients and their contacts. No procedures are available for identifying persons (other than those with immunodeficiency) who are at risk for such adverse reactions. Although the risk for vaccine-associated paralytic poliomyelitis (VAPP) is minimal, vaccinees (or their parents) and their susceptible, close, personal contacts should be informed of this risk (see Table in the guideline document). The overall risk for VAPP is approximately one case in 2.4 million doses of OPV vaccine distributed, with a first-dose risk of one case in 750,000 first doses distributed. Administration of OPV can cause VAPP that results in death, although this is rare.

Available evidence indicates that administration of OPV does not measurably increase the risk for Guillain-Barré Syndrome, a type of ascending inflammatory polyneuritis.

Subgroups Most Likely to be Harmed:

Immunodeficient persons, particularly those who have B-lymphocyte disorders that inhibit synthesis of immune globulins (i.e., agammaglobulinemia and hypogammaglobulinemia), are at greatest risk for vaccine-associated paralytic

poliomyelitis (VAPP) (3,200-fold to 6,800-fold greater than the risk for immunocompetent oral poliovirus vaccine [OPV] recipients).

Infants, adolescents or adults with an immunodeficiency disorder of any etiology (including infection with human immunodeficiency virus [HIV]), or recipients of immunosuppressive chemotherapy (e.g., cancer chemotherapy, or systemic steroid use) should only receive inactivated poliovirus vaccine (IPV). Immunologically competent persons who live in a household with a person who has or is suspected to have any of these conditions should also only receive IPV because OPV virus can spread secondarily.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Centers for Disease Control and Prevention. Poliomyelitis prevention in the United States. MMWR Recomm Rep 2000 May;49(RR-5):1-22. [81 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Jan 24 (revised 2000 May 19)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members: John F. Modlin, M.D. (Chairman); Dixie E. Snider, Jr., M.D., M.P.H. (Executive Secretary); Richard D. Clover, M.D.; David W. Fleming, M.D.; Mary P. Glode, M.D.; Marie R. Griffin, M.D.; Fernando A. Guerra, M.D., M.P.H.; Charles M. Helms, M.D., Ph.D.; David R. Johnson, M.D., M.P.H.; Chinh T. Le, M.D.; Paul A. Offit, M.D.; Jessie L. Sherrod, M.D.; Bonnie M. Word, M.D.

CDC staff members: D. Rebecca Prevots, Ph.D., M.P.H.; Roger K. Burr, M.D., M.P.H.; Roland W. Sutter, M.D., M.P.H.&T.M.; Trudy V. Murphy, M.D.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

Update: These revised recommendations replace recommendations on poliomyelitis issued in 1982 (Poliomyelitis prevention: recommendations of the Immunization Practices Advisory Committee [ACIP]. Morbid Mortal Wkly Rep MMWR 1982;31), 1987 (Poliomyelitis prevention: enhanced-potency inactivated poliomyelitis vaccine-supplementary statement: recommendations of the Immunization Practices Advisory Committee [ACIP]. Morbid Mortal Wkly Rep MMWR 1987;36:795-8) and 1997 (Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine. Recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR Morb Mortal Wkly Rep 1997 Jan 24;46(RR-3):1-25).

GUIDELINE AVAILABILITY

Electronic copies: An HTML Text version is available from the Centers for Disease Control and Prevention (CDC) Web site.

Also available (in Portable Document Format [PDF]) from the Centers for Disease Control and Prevention (CDC) Web site.

Print copies: Available from CDC, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 5, 2000. The information was verified by the guideline developer on August 4, 2000.

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